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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,813	03/10/2004	Albert Crum	2417-1-012	7474

23565 7590 06/29/2005

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EXAMINER	
JUNG, UNSU	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/797,813	CRUM, ALBERT	
	Examiner	Art Unit	
	Unsu Jung	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-36* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, drawn to a method for assessing the need for treatment of a subject with an anti-oxidant, classified in class 424, subclass 94.1, for example.

II. Claims 7-13, drawn to a method for measuring the effectiveness of therapy with an anti-oxidant in a subject receiving treatment with an anti-oxidant, classified in class 424, subclass 94.2, for example.

III. Claim 21, drawn to a method for determining the amount of IMMUNE FORMULATION 100™ or IMMUNE FORMULATION 200™, which is necessary to increase glutathione synthesis or re-synthesis in a patient in need of such therapy, classified in class 424, subclass 278.1, for example.

IV. Claim 22, drawn to a method for determining the amount of IMMUNE FORMULATION 100™ or IMMUNE FORMULATION 200™, which is necessary to reduce urine pyroglutamic acid in a patient in need of such therapy, classified in class 514, subclass 2, for example.

V. Claim 23, drawn to a method for determining the amount of IMMUNE FORMULATION 100™ or IMMUNE FORMULATION 200™ that is necessary to reduce urine lipid peroxide in a patient in need of such therapy, classified in class 562, subclass 575, for example.

VI. Claim 24, drawn to a method for determining an orally anti-oxidative effective amount of IMMUNE FORMULATION 100™ or IMMUNE FORMULATION 200™ sufficient to diminish urine lipid peroxide and pyroglutamic acid levels and concurrently increase blood plasma glutathione levels, classified in class 424, subclass 279.1, for example.

VII. Claim 25, drawn to a method for establishing the interdependence of lipid peroxides, pyroglutamic acid, glutathione, and immune cell number and/or function in a subject suffering from oxidative stress, classified in class 562, subclass 573, for example.

VIII. Claim 26, drawn to a method for determining and immune enhancing effective amount of IMMUNE FORMULATION 100™ or IMMUNE FORMULATION 200™ sufficient to normalize CD4+, CD8+ T cell numbers and natural killer cell activity in a subject suspected of experiencing oxidative stress, classified in class 424, subclass 283.1, for example.

IX. Claims 27 and 28, drawn to a method for determining an orally anti-oxidative effective amount and an immune enhancing effective amount of IMMUNE FORMULATION 100™ or IMMUNE FORMULATION 200™ sufficient to normalize lipid peroxides, pyroglutamic acid and glutathione levels in a subject suspect of experiencing oxidative stress, wherein the normalization of lipid peroxides, pyroglutamic acid and glutathione levels results in immune enhancement, classified in class 424, subclass 280.1, for example.

X. Claim 29-32, drawn to a kit for measuring oxidative stress in a subject, classified in class 435, subclass 7.1, for example.

XI. Claims 33, drawn to a method for providing a course of therapy for an individual suspected or know to be suffering from oxidative stress, classified in class 424, subclass 184.1, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-IX and XI are independent and patentably distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method of Group I includes a step of determining that the levels of lipid peroxide and pyroglutamic acid in a sample of body fluid from a subject suspected of needing anti-oxidative treatment and glutathione in blood plasma outside the normal range are indicative of a need for anti-oxidant treatment, which is not required by the methods of Groups II-IX and XI. The method of Group II includes a step of determining that the presence of normal levels of lipid peroxide and pyroglutamic acid in a sample of body fluid from a subject being treated with anti-oxidative and blood plasma glutathione are an indication of effectiveness of the anti-oxidant therapy, which is not required by the methods of Groups I, III-IX, and XI. The method of Group III includes a step of determining that the presence of normal levels of lipid peroxide and pyroglutamic acid in a sample of body fluid from a subject

being treated with anti-oxidative and blood plasma glutathione are an indication of efficiency of utilization of the anti-oxidant, which is not required by the methods of Groups I, II, IV-IX, and XI. The method of Group IV includes correlating normalization of lipid peroxide and pyroglutamic acid levels in body fluid samples with the synthesis or re-synthesis of glutathione in the patients receiving IMMUNE FORMULATION 100™ or IMMUNE FORMULATION 200™, which is not required by the methods of Groups I-III, V-IX, and XI. The method of Group V includes correlating reductions of pyroglutamic acid to normal levels in body fluid samples with the amount of IMMUNE FORMULATION 100™ or IMMUNE FORMULATION 200™ sufficient to achieve a beneficial effect, which is not required by the methods of Groups I-IV, VI-IX, and XI. The method of Group VI includes determining whether a decrease in lipid peroxide and pyroglutamic acid levels correlates with an increase in glutathione levels and the correlation establishes an orally anti-oxidative effective amount of IMMUNE FORMULATION 100™ or IMMUNE FORMULATION 200™, which is not required by the methods of Groups I-V, VII-IX, and XI. The method of Group VII includes measuring the number of CD4+ and CD8+ T cells and the natural killer cell activity from the cellular component of whole blood obtained from a subject suspected of being under oxidative stress and providing support for the interdependence of the level of oxidative stress in the subject and immune cell number and/or function, which are not required by the methods of Groups I-VI, VIII, IX, and XI. The method of Group VIII includes correlating between the does of IMMUNE FORMULATION 100™ or IMMUNE FORMULATION 200™ that is sufficient to normalize CD4+, CD8+ T cell numbers and natural killer cell

activity establishes an immune enhancing effective amount of IMMUNE FORMULATION 100™ or IMMUNE FORMULATION 200™, which is not required by the methods of Groups I-VII, IX, and XI. The method of Group IX includes determining whether a decrease in urinary lipid peroxide and pyroglutamic acid levels correlates with an increase in glutathione levels, and whether the normalization of the levels of all threes of these products relates to a normalization of CD4+ and CD8+ T cells numbers and normalization of natural killer cell activity, which is not required by the methods of Groups I-VIII and XI. The method of Group XI includes determining the identity and levels of at least three markers of oxidative stress in a sample of body fluid from individuals suspected or known to be suffering from oxidative stress and selecting the appropriate course of therapy for the individual, which are not required by the methods of Groups I-IX. Therefore, the methods of Groups I-IX and XI have different modes of operation, function and effects.

Inventions X and I-IX, XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process. For example, the product of Group X can be used in methods of Groups I-IX and XI.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art because of their recognized divergent subject matter, searches for one group are not required for the others, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Unsu Jung whose telephone number is 571-272-8506. The examiner can normally be reached on M-F: 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Patent Examiner
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06/23/05